Chemical Products Corporation

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Rec'd 8/21/02

Dr. Scott A. Masten
Office of Chemical Nomination and Selection
NIEHS/NTP
P.O. Box 12233
MD A3-07
Research Triangle Park, North Carolina 27709

Re: Comments Relating to Sodium Metasilicate [6834-92-0], a Substance Recommended for Toxicological Inhalation Studies by the ICCEC - 67 FR 113 pages 40329-40333 (June 12, 2002)

Dear Dr. Masten:

These comments are submitted by Chemical Products Corporation (CPC), a manufacturer of Sodium Metasilicate located in Cartersville, Georgia. They concern the listing of Sodium Metasilicate (CAS# 6834-92-0) as a material nominated for study by the National Toxicology Program (NTP) to determine subchronic inhalation effects and evaluate respiratory hypersensitivity potential.

Sodium Metasilicate, also known as Disodium Metasilicate and Disodium Trioxosilicate, is commercially available as both the anhydrous solid and as solid pentahydrate crystals containing 42% water by weight. These highly alkaline water-soluble silicate products are used primarily as alkaline builders in industrial detergents. These are granular products, that are screened during manufacture such that they typically pass through U.S. Standard 20 mesh screens and are retained on U.S. Standard 48 mesh screens. In many formulations, liquid organic surfactants are admixed with the dry Sodium Metasilicate which absorbs the liquid to allow the formulation to remain a flowable, but non-dusting powder.

Although the Sodium Metasilicate products had been transported in commerce for many decades without incident, both the Sodium Metasilicate, Anhydrous and Sodium Metasilicate, Pentahydrate products were reclassified as DOT hazardous materials several years ago. They are regulated in commerce by DOT as corrosive materials. The Sodium Metasilicate, Pentahydrate is shipped under the DOT proper shipping name "Disodium Trioxosilicate", in Packing Group III; the Sodium Metasilicate, Anhydrous is shipped under the DOT proper shipping name "Corrosive Solid, basic, inorganic, n.o.s.", in Packing Group II. The corrosive designation by DOT demonstrates that contact of these materials with intact rabbit skin in the presence of moisture has been found to result in complete skin destruction.

The attached pages from the international uniform chemical information database (second edition of IUCLID on CD-ROM, European Commission Joint Research Centre, Institute for Health and Consumer Protection, EUR 19559 EN, 2000) demonstrate that Sodium Metasilicate is regarded in Europe as a non-sensitizing material when incorporated into the products to which there is significant human exposure.

CPC has been manufacturing Sodium Metasilicate at its Cartersville, Georgia facility since 1963. Thus, we feel that we have an extensive knowledge of industrial experience with this material. We have not experienced any instances of hypersensitivity associated with Sodium Metasilicate. We question the decision by NIOSH to nominate sodium metasilicate as a substance to be studied by NTP for subchronic inhalation and respiratory hypersensitivity effects because we do not believe that there is a significant exposure of industrial workers to sodium metasilicate dust. Even very low concentrations of sodium metasilicate dust in air produce a very sharp, unpleasant, and even painful, sensation when that air is breathed. We believe that the corrosive effect on mucous membranes resulting from the alkalinity of Sodium Metasilicate, and the resulting extreme discomfort, acts to prevent significant industrial exposure to Sodium Metasilicate dust.

Inhaled soluble silicates rapidly dissolve in the lungs, pass into the blood and are rapidly excreted in the urine (Michon, R.; Sue, P.; Merinis, J., "Hygiene Du Travail.-Metabolisme de la silice et des silicates inhales par l'animal, suivi a l'aide de ^{31}Si." Comptes Rendus, 243, 1956, p. 2194). If the alkalinity of sodium metasilicate were to be neutralized to physiological pH, the Sodium Metasilicate would be transformed into different substances, amorphous silica and a sodium salt. Information about inhalation of amorphous silica already exists.

In conclusion, we respectfully suggest that Sodium Metasilicate is not a suitable candidate to nominate for subchronic inhalation and respiratory hypersensitivity study because of very limited industrial exposure to Sodium Metasilicate dust and the existence of sufficient information concerning the amorphous silica that precipitates from a solution of Sodium Metasilicate at physiological pH.

Thank you for the opportunity to comment on this nomination. If you have questions regarding anything in this letter, please telephone me at 770-382-2144.

Sincerely,

Jerry Cook

Jerry A. Cook
Technical Director

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 6834-92-0
CAS No.	6834-92-0
EINECS Name	disodium metasilicate
EINECS No.	229-912-9
Molecular Formula	H2O3Si.2Na

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

Creation date: 19-FEB-2000

Number of Pages: 52

Chapters: all

Edition: Year 2000 CD-ROM edition

Flags: non-confidential

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

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4.6.2 Toxicity to Terrestrial Plants

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4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

-

4.7 Biological Effects Monitoring

-

4.8 Biotransformation and Kinetics

-

4.9 Additional Remarks

Remark: Soluble silicates, upon dilution are indistinguishable from natural dissolved silica. However the pH of most silicate solutions is above the acceptable limits for direct discharge to sewers or water courses

Source: MEL Chemicals MANCHESTER

5.2.2 Eye Irritation

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: irritating
EC classificat.:
Method: other: FHSA Draize Eye Contact Test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: A sodium metasilicate solution of a concentration of 10% wt. was tested. In analogy to the corrosive effects concentrated sodium silicate solutions exert on the skin, e. g. sodium silicate solution of a molar ratio of 1.6 and a concentration of 53.5%, it is estimated that more concentrated solutions (> 10%) of sodium metasilicate are corrosive to the eye.
Source: Henkel KGaA Duesseldorf

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Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: corrosive
EC classificat.:
Method: other: in-vitro eye irritation
Year: **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Remark: Sodium metasilicate powder of 20% water content was applied for 10 sec onto the enucleated eye.
Source: Henkel KGaA Duesseldorf

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5.3 Sensitization

Type: other: expert judgement
Species:
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:**
Test substance: other TS
Remark: The references are expert judgements on the sensitization potential of sodium metasilicate containing laundary products, but do not give primary test data for the pure

substance.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Sodium metasilicate (30%) containing laundry product.

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Type: other: expert judgement
Species:
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:**
Test substance: other TS
Remark: The references are expert judgements on the sensitization potential of sodium metasilicate containing laundary products, but do not give primary test data for the pure substance.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Sodium metasilicate (30%) containing laundry product.

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Type: other: expert judgement
Species:
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:**
Test substance: other TS
Remark: The references are expert judgements on the sensitization potential of sodium metasilicate containing laundary products, but do not give primary test data for the pure substance.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Sodium metasilicate (30%) containing laundry product.

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5.4 Repeated Dose Toxicity

Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: drinking water
Exposure period: 2 years
Frequency of treatment: continuous
Post. obs. period: no data
Doses: = or > 792 mg/kg/day (the quoted maximum safety concentration)
Control Group:
NOAEL: = 792 mg/kg bw
Method: other: not specified
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Data are from an abstract submitted at the 4th International Congress of Toxicology in Tokyo (1986). The numbers of animals or the dose range for the chronic study were not quoted. No further details available.
Result: The authors state: "No specific change was observed in the two-year study. In a subchronic study with even higher doses, slight degenerative changes in the epithelium of renal tubules were occasionally observed." The maximum safety concentration (NOAEL) for sodium metasilicate in drinking water is quoted as 792 mg/kg/day.
Source: Henkel KGaA Duesseldorf

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5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: Salmonella typhimurium reverse mutation assay
Concentration: 1.6-5000 ug/plate
Metabolic activation: with and without
Result: negative
Method: OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year: **GLP:** yes
Test substance: other TS
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! A disinfectant was tested. The product contains, besides inorganic builders, surface active substances and a bacteriocide, substantial amounts of sodium metasilicate.

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5.6 Genetic Toxicity 'in Vivo'

Type: other: not known
Species: other: not known **Sex:**
Strain:
Route of admin.:
Exposure period:
Doses: not mentioned
Result:
Method: other: not known
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: It is assumed that the authors came to the conclusion that "sodium metasilicate has no mutagenicity" on the basis of tests that they conducted in parallel to their two-year chronic study, but did not publish. Therefore, no further details are available. It is not even clear, if the authors refer to genetic toxicity in-Vivo or in-Vitro.
Source: Henkel KGaA Duesseldorf

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5.7 Carcinogenicity

Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: drinking water
Exposure period: 2 years
Frequency of treatment: continuous
Post. obs. period: no data
Doses: no data specified
Result:
Control Group: no data specified
Method: other: not known
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Result: Sodium metasilicate is stated by the authors to be not carcinogenic. No further details are available.
Source: Henkel KGaA Duesseldorf

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5.9 Developmental Toxicity/Teratogenicity

Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: drinking water
Exposure period: 2 years
Frequency of treatment: continuous
Duration of test: 2 years
Doses: not explict mentioned, probably "high doses" as stated for the two-year chronic toxcicity study
Control Group: no data specified
Method: other: not specified
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Result: The authors state: "Sodium metasilicate has no teratogenicity", but no details on methodology and doses were given. It is assumed that the authors came to the above mentioned conclusion on the basis of their two-year chronic toxicity study.
Source: Henkel KGaA Duesseldorf

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5.10 Other Relevant Information

Type: Excretion
Remark: The rate and extent of urinary excretion of silicon was determined in rats after oral administration of sodium silicate. The substance was given in doses of 0, 40, 200 or 1.000 mg/kg body weight. Urinary silicon excretion increased rapidly after dosing and peak excretion rates occured within 24 h. Sodium silicate was excreted by a first order kinetic, with a half-life of 24 h.
Source: Henkel KGaA Duesseldorf

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5.11 Experience with Human Exposure

Remark: Under very specific circumstances aspiration of vomitted sodium "meta"silicate solution has led to immediate (1 h) death by suffocation. A case report of fatal ingestion of 0.5 l of sodium "meta"silicate containing egg preserving solution is described.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Although the authors state that sodium metasilicate was used (in form of an egg preserving solution from a local drug store), the relative low pH of 12.5 makes it more likely that a waterglass solution of a molar ratio of 1.6-2.5 was actually used (see Schleyer and Blumberg, page 52, for pH dependence vs. ratio and Winter et al., for pH dependence vs. concentration).

(1) (58) (11)

Remark: Ingestion of dry or liquid formulations containing 20% or higher concentrations of sodium metasilicate can result in serious health injuries. Depending on amount and time of exposure perforation or stricture formation of the esophagus are possible.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Dishwashing detergents, containing 20-40% sodium metasilicate.

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Remark: Ingestion of dry or liquid formulations containing 20% or higher concentrations of sodium metasilicate can result in serious health injuries. Depending on amount and time of exposure perforation or stricture formation of the esophagus are possible.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Dishwashing detergents, containing 20-40% sodium metasilicate.

(59)

Remark: Ingestion of dry or liquid formulations containing 20% or higher concentrations of sodium metasilicate can result in serious health injuries. Depending on amount and time of exposure perforation or stricture formation of the esophagus are possible.
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Dishwashing detergents, containing 20-40% sodium metasilicate.

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